5.0 510(k) Summary

Owner/Manufacturer:	Terumo BCT, Inc. 10811 W. Collins Avenue Lakewood, Colorado 80215
Contact Person:	Patti Arndt Senior Regulatory Affairs Specialist Phone: (303) 231-4832
Date of Summary Preparation:	November 27, 2012
Trade Name:	Spectra Optia® Apheresis System
Common Name:	Apheresis System
Classification Name:	Automated Blood Cell Separator
Product Code:	GKT
Predicate Device:	Spectra Optia Apheresis System – Mononuclear Cell Collection Protocol

Device Description: The Spectra Optia Apheresis System is a centrifugal system that separates whole blood into its cellular and plasma components. The device is comprised of three major sub-systems: (1) the apheresis machine itself (centrifuge, pumps, valves, etc.), (2) a sterile, single-use, disposable tubing set and, (3) embedded software. In this application, the system collects mononuclear cells from the peripheral blood of donors and patients.

The system's Mononuclear Cell (MNC) Collection Protocol has been enhanced to improve the system's flexibility with respect to the collection and management of plasma. The system's disposable Collection Set and embedded software have been modified to allow the operator to direct concurrently collected plasma to the disposable set's Plasma Bag (as before), back to the patient (as before), and now also to the disposable set's MNC Collection Bag. In addition, system operators may now transfer plasma directly from the Plasma Bag into the MNC Collection Bag – during or after the MNC collection procedure. This software-controlled modification affects the routing of fluids within the disposable set's cassette, but does not change the system's essential functionality (i.e., its ability to separate blood into its components and to safely and efficiently collect mononuclear cells). With this enhancement, system operators and laboratory personnel can more easily add plasma to the collected MNC product, as required for product storage and shipping.

Intended Use:

The Spectra Optia Apheresis System, a blood component separator, may be used to perform procedures for the collection of mononuclear cells from peripheral blood.

Technological Comparison:

The system's base technology is not changed by the Spectra Optia Collection Set's modified flow path or the software changes that control and support the enhancement.

Discussion of Non-clinical Data:

The correct functioning of the system's enhanced ability to collect and transfer plasma was verified through the following activities:

- Physical testing of the modified Spectra Optia Collection Set to ensure that the modified flow path through the cassette functioned as designed.
- Software code reviews and unit tests to ensure that algorithms and other code were written correctly and yielded the expected results.
- Integration tests to ensure that the modified disposable set and software functioned correctly.
- Simulated use tests to ensure that the system's ability to safely and efficiently collect mononuclear cells was not affected by the change.

Discussion of Clinical Data:

Extensive laboratory testing was conducted to verify and validate the functionality and effectiveness of the new feature. Clinical validation data were not necessary, as the modification did not impact the implementation, control, or effectiveness of the system for its intended use of mononuclear cell collection.